

## **Agenda Day 1**

### **FDA - OTC Part 15 Hearing June 28, 2000**

**Holiday Inn, Gaithersburg, MD**

**8:30am**      **Opening Remarks**  
**Robert DeLap M.D., Ph.D., Director, Office of Drug Evaluation V, CDER**

#### **SESSION 1A: PROCESS ISSUES**

**8:45am**      **Consumer Healthcare Products Association (CHPA)**  
**Michael D. Maves, M.D., M.B.A., President**  
**Eve E. Bachrach, Esq. Senior Vice President, General Counsel and Secretary**  
**R. William Soller, Ph.D. Senior Vice President & Director of Science & Technology**

**9:10am**      **The Cosmetic, Toiletry, and Fragrance Association**  
**Thomas J. Donegan, Jr., Vice President – Legal and General Counsel, CTFA**  
**James Leyden, M.D., University of Pennsylvania School of Medicine**

**9:30am**      **Francesco International**  
**Steve Francesco, President and Founder**

**9:50am**      **National Consumers League**  
**Linda Golodner, President**  
**Brett Kay, Program Associate, Health Policy**

**10:10am – 10:25am**      **Break**

**10:25am**      **Kaiser Permanente**  
**Anthony Barrueta, Counsel, Government Relations**

**10:40am**      **Buchanan and Ingersoll, Attorneys at Law**  
**Robert G. Pinco and Mary Johnson**

**10:55am**      **Steinberg and Associates, Inc.**  
**David C. Steinberg**

**11:10am**      **American Pharmaceutical Association**  
**Rebecca W. Chater, RPh**

**11:25am**      **National Community Pharmacists Association**  
**Doug Hoey, Vice President, Professional and Practice Affairs**

**11:40am**      **Dickinson, Dickinson and Company**  
**BD Consumer Healthcare**  
**Anna M. Longwell, Esq., Director, Corporate Regulatory Affairs**

**11:55am**      **American College of Obstetricians and Gynecologists**  
**Michael Greene, M.D.**

**12:00am**      **Lunch Break**

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**LST 3**

## **SESSION 1B: PROCESS ISSUES**

- 1:30pm**      **Public Citizen's Health Research Group**  
**Sidney Wolfe, M.D.**
- 1:40pm**      **MedImpact**  
**Schumarry Chao, M.D., M.B.A.**
- 1:50pm**      **PEGUS Research**  
**David C. Bradford, Ph.D., MPH, Dept. of Family and Preventive Medicine**  
**University of Utah School of Medicine**
- 2:00pm**      **National Women's Health Network**  
**Amy Alhna, Program and Policy Director**
- 2:10pm**      **Pharmaceutical Research and Manufacturers of America**  
**Matthew Van Hook, Deputy General Counsel**
- 2:20pm**      **Peter Barton Hutt**
- 2:30pm**      **Break**
- 3:00pm**      **Smith Kline Beecham**  
**John Dent, Ph.D., Vice President of Research and Development**
- 3:10pm**      **Ammsys Research, Inc.**  
**Gerald F. Dunaway, Ph.D., President**

## **SESSION 2: MISCELLANEOUS**

- 3:20pm**      **Infectious Diseases Society of America (IDSA)**  
**Frederick P. Sparling, M.D., Chairman**
- 3:30pm**      **Cholestech Corporation**  
**Warren E. Pinchert II, President and Chief Executive Officer**
- 3:40pm**      **Chris Kahlenborn, M.D.**

## **Agenda Day 2**

### **FDA- OTC Part 15 Hearing June 29, 2000**

#### **SESSION 3: ORAL CONTRACEPTIVES**

- 8:30am American Life League, Inc.  
Judie Brown, President
- 8:35am Why Life?  
Cathy Brown, Director
- 8:40am American Bioethics Advisory Commission  
Father Joseph C. Howard, Jr., M.Div.
- 8:45am Rosalie M. Gross

#### **SESSION 4: EMERGENCY CONTRACEPTIVES**

- 8:50am Reproductive Health Technologies Project  
Kirsten Moore, Project Director
- 8:55am Gynetics Inc.  
Jack E. Stover, Chief Operating and Financial Officer
- 9:00am American Society for Emergency Contraception  
Tara Shochet, MPH, Deputy Director
- 9:05am Population Council  
Beverly Winikoff, M.D., M.P.H.
- 9:10am NARAL  
Elizabeth A. Carendish, Legal Director
- 9:15am Family Health International  
Elizabeth Raymond

#### **SESSION 5: CARDIOLOGY – VASCULAR DRUG CLASS ISSUES**

- 9:25am Lipid Nurse Task Force  
Suzanne Hughes, President Elect
- 9:35am Merck Research Laboratories  
Jeffrey L. Anderson, M.D., Chief, Division of Cardiology  
Professor of Internal Medicine, University of Utah School of Medicine
- 9:45am Bristol Myers Squibb  
Lorie G. Rice, MPH, UCSF School of Pharmacy
- 9:55 Break
- 10:20am Jerome D. Cohen, M.D., FACC  
Saint Louis University
- 10:30am Heeger and Barnett, LLP  
Bruce Philip Barnett, M.D. and Mr. Calabio

10:40am American College of Cardiology  
Edward Frohlich, M.D., FACC

## **SESSION 6: ANTI-MICROBIALS AND ANTIBIOTIC ISSUES**

10:50am Alliance for the Prudent Use of Antibiotics  
Kathleen T. Young, Executive Director

11:00am Alliance for Microbicide Development  
Gretchen F. Kidder, Alliance Research Associate

11:10am ReProtect, LLC  
Thomas R. Moench, M.D., Medical Director

11:20am EPlcyte Pharmaceutical, Inc.  
Kevin J. Whaley, Ph.D., Director

11:30am Lunch

## **SESSION 7: ALLERGY AND ASTHMA DRUG ISSUES**

1:10pm Allergy and Asthma Network  
Mothers of Asthmatics, Inc.  
Nancy Sander, President and Founder

1:20pm Linda Borschuk  
Patient Advocate

1:30pm Blue Cross of California/ Well Point Health Networks  
Robert C. Seidman, Pharm.D., MPH, Vice President, Pharmacy

## **SESSION 8: LABEL COMPREHENSION ISSUES**

1:40pm Q2 Marketing Research, Inc.  
Stephen J. Hellebusch, Ph.D.

1:50pm Hill Top Research  
Susan Shellabarger, Senior Director, Business Development, OTC Products

## **SESSION 9: PROCESS ISSUES**

2:00pm Blue Cross Blue Shield Association  
Allan Korn, M.D., Senior Vice President Clinical Affairs and Chief Medical Officer

2:10pm Consumer Healthcare Products Association (CHPA)  
Randy P. Juhl, Ph.D., University of Pittsburgh, Dean and Professor, School of  
Pharmacy & Associate Vice Chancellor for Research Conduct

2:20pm - 2:40pm Break

## **SESSION 10: OPEN PUBLIC HEARING**

2:40pm - 4:00pm

Please register at the front desk if you are interested in speaking at this session. Registration does not guarantee that you will be speaking. We will post the list of speakers before this session begins. Priority will be given to persons and organizations who have not already spoken. In general, one should not plan on speaking longer than 5 minutes.

**Please pick up a form at the desk and turn it back in before noon on June 29, 2000 if you are interested in participating in this session.**